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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,381	07/11/2001	Charles W. Hewitt	266/156	8315

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/10/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/903,381

Applicant(s)

HEWITT, CHARLES W.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following species is required under 35 U.S.C. 121:

Group I, claims 1-22, drawn to a composition and a kit comprising at least one segment of a tissue that has been subjected to a treatment that reproducibly results in a predetermined, measurable amount of apoptosis in the segment, classified in class 435, subclasses 6 and 7.1.

Group II, claim 23, drawn to a kit comprising at least one segment of a tissue that has been subjected to a treatment that reproducibly results in a predetermined, measurable amount of apoptosis in the segment, and one or more additional reagents, classified in class 435, subclasses 6 and 7.1 .

Group III, claim 24, drawn to a kit comprising at least one segment of a tissue that has been subjected to a treatment that reproducibly results in a predetermined, measurable amount of apoptosis in the segment, and an extract of the soluble proteins of the tissue segment, classified in class 435, subclasses 6 and 7.1.

Group IV, claim 25, drawn to a kit comprising at least one segment of a tissue that has been subjected to a treatment that reproducibly results in a predetermined, measurable amount of apoptosis in the segment, and a concentrated sample of culture medium, classified in class 435, subclasses 6 and 7.1 .

In addition, upon election of any one of groups I-IV, further election of the following species is required:

1) Any one of the tissues of claim 2 and claim 14 or a combination of tissues, wherein a single combination of tissues constitutes a single species.

2) Determine the increase in a single protein or mRNA encoding single protein recited in claim 6, or determine the decrease in a single protein or mRNA encoding single protein recited in claim 9.

3) Treatment using microgravity bioreactor, or microgravity bioreactor and dexamethasone, or biological stress comprising ~~c~~alcing the tissue.

4) TUNEL staining or immunological evaluation.

The inventions are distinct, each from each other because of the following reasons:

The products of groups I-IV are patentably distinct, because the products of groups I-IV comprises additional compounds not found in group I.

The species tissues are distinct, because they are drawn to different tissues with different properties.

The species of proteins or mRNAs of claim 6 and 9 are distinct because they are have different structure.

The species microgravity bioreactor, or microgravity bioreactor and dexamethasone are distinct because the microgravity bioreactor and dexamethasone has an additional compound not found in the the microgravity bioreactor. Further, the species biological stress is distinct from the species microgravity bioreactor, or microgravity bioreactor and dexamethasone because they have different properties.

The species TUNEL staining or immunological evaluation are distinct, because they are different methods with different method steps and reagent used.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if

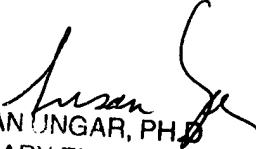
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one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

MINH TAM DAVIS

August 24, 2002